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STATEMENT BY APPLICANT**

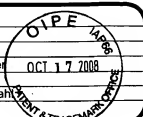
Date Submitted: October 17, 2008

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Sheet 1 of 3

**Complete if Known**

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10/677,857         |
| Filing Date            | 10/3/2003          |
| First Named Inventor   | Eugene R. Cooper   |
| Art Unit               | 1651               |
| Examiner Name          | Thane E. Underdahl |
| Attorney Docket Number | 029318-0981        |

**U.S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|--------------------|----------|--|--------------------------------|--|--|
|                    |          | Number-Kind Code <sup>2</sup> (if known) |                                |  |  |
|                    | A1       | 5,542,935                                | 08/1996                        | Unger et al.                                       |  |
|                    | A2       | 4,562,069                                | 12/1985                        | Hegasy et al.                                      |  |
|                    | A3       | 4,665,081                                | 05/1987                        | Doi et al.   |  |
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|                    | A5       | 6,231,888                                | 05/2001                        | Lerner et al.                                      |  |
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| Examiner Initials* | Cite No. | Foreign Patent Document  | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Documents | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>3</sup> |
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|                    |          | Country Code <sup>5</sup> Number <sup>2</sup> Kind<br>Code <sup>6</sup> (if known) |                                |   |  |                |
|                    | B1       | EP 0 220 760 A2  | 10/1985                        | Eurand Italia S.p.A.                                |  |                |
|                    | B2       | WO 00/18374  | 04/2000                        | Swanson et al.                                      |  |                |
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|                    | B5       | WO 2005/000273 A1  | 01/2005                        | Olivieri et al.                                     |  |                |

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Sheet 2 of 3

**Complete if Known**

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| Filing Date            | 10/3/2003          |
| First Named Inventor   | Eugene R. Cooper   |
| Art Unit               | 1651               |
| Examiner Name          | Thane E. Underdahl |
| Attorney Docket Number | 029318-0981        |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No.† | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.                                  | T <sup>§</sup> |
|--------------------|-----------|---|----------------|
|                    | C1        | MATSUMOTO ET AL., "Physical Properties of Solid Molecular dispersions of Indomethacin with Poly(vinylpyrrolidone) and Poly(vinylpyrrolidone-co-vinyl-acetate) in Relation to Indomethacin Crystallization," <i>Pharmaceutical Research</i> (1999), Vol. 16, No. 11, pp. 1722-1728, XP000987250. |                |
|                    | C2        | HULSMANN ET AL., "Melt extrusion - an alternative method for enhancing the dissolution rate of 17 $\beta$ -estradiol hemihydrate," <i>European Journal of Pharmaceutics and Biopharmaceutics</i> (2000), Vol. 49, No. 3, pp. 237-242, XP004257163.  |                |
|                    | C3        | VOJNOVIC ET AL., "Formulation and evaluation of vinylpyrrolidone/vinylacetate copolymer microspheres and griseofulvin," <i>J. Microencapsulation</i> (1993), Vol. 10, No. 1, pp. 89-99, XP000334996.  |                |
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|                    | C5        | ZINGONE ET AL., "Characterization and dissolution study of solid dispersions of theophylline and indomethacin with PVP/VA copolymers," <i>STP Pharma Sciences</i> (1992), Vol. 2, No. 2, pp. 186-192, XP002111752.  |                |
|                    | C6        | Singh et al., Nimesulide, Analytical Profiles of Drug Substances and Excipients, (2001), Vol. 28, pp. 197-249.  |                |
|                    | C7        | The Merck Index, 1996, Merck & Co., 12 <sup>th</sup> Edition, pp. 2518-2531.  |                |
|                    | C8        | Office Action for co-pending related U.S. Application No. 10/697,716, dated March 18, 2008.   |                |
|                    | C9        | Office Action for co-pending related U.S. Application No. 10/712,259, dated March 17, 2008.   |                |
|                    | C10       | Office Action for co-pending related U.S. Application No. 11/980,586, dated September 22, 2008.   |                |
|                    | C11       | Office Action for co-pending related U.S. Application No. 11/979,231, dated September 18, 2008.   |                |
|                    | C12       | Office Action for co-pending related U.S. Application No. 09/337,675, dated September 27, 2007.   |                |
|                    | C13       | Office Action for co-pending related U.S. Application No. 10/701,064, dated February 7, 2008.   |                |

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Signature

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|  |   | Filing Date              | 10/3/2003          |
|  |   | First Named Inventor     | Eugene R. Cooper   |
|  |   | Art Unit                 | 1651               |
|  |   | Examiner Name            | Thane E. Underdahl |
| Date Submitted: October 17, 2008                         |   | Attorney Docket Number   | 029318-0981        |
| (use as many sheets as necessary)                        |   |                          |                    |
| Sheet  | 3 | of                       | 3                  |

**NON PATENT LITERATURE DOCUMENTS**

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|--------------------|-----------------------|--|----------------|
|                    | C14                   | Office Action for co-pending related U.S. Application No. 11/650,412, dated March 21, 2008.  |                |
|                    | C15                   | Office Actions for co-pending related U.S. Application No. 10/697,703, dated April 4, 2008.  |                |
|                    | C16                   | Office Actions for co-pending related U.S. Application No. 10/697,703, dated September 5, 2007.  |                |
|                    | C17                   | Office Action for related U.S. Application No. 11/592,264, dated September 27, 2007.   |                |

|                    |                   |                 |            |
|--------------------|-------------------|-----------------|------------|
| Examiner Signature | /Thane Underdahl/ | Date Considered | 01/19/2009 |
|--------------------|-------------------|-----------------|------------|

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